DRAFT RECOMMENDATIONS REGARDING INFORMED CONSENT AND WAIVER OF CONSENT

For Consideration by SACHRP on October 9, 2012

Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

In accordance with the provisions of the charter for the Secretary's Advisory Committee on Human Research Protections (SACHRP), I respectfully submit for your consideration a recommendation relative to Department of Health and Human Services Regulation for the Protection of Human Subjects as codified in 45 CFR Part 46. This letter represents the xxx in a series of recommendations from SACHRP.

The informed consent requirements found in HHS 45 CFR 46 Regulation for the Protection of Human Subjects in Research provide a bedrock protection for individuals participating in research studies. While the regulatory default for non-exempt research is to obtain and document the informed consent of all participants, the regulations anticipated scenarios where this default requirement would be inappropriate given the proposed methodology, the context in which the research would be conducted or the subject population. The regulations included provisions allowing IRBs to waive some or all elements of informed consent when specific conditions have been met.

In practice, the regulations governing waivers of informed consent at §46.116(d) are constructed in such a way that IRBs have variable understanding of when waivers of selected elements of consent are appropriate. As a result, IRBs have frequently required investigators to include information in consent documents that adds little value to the consent process, for example, a statement that "the only alternative is not to participate in this research." In fact, by adding length to consent documents and including irrelevant information it could be argued that the effectiveness of the consent process is diminished. In addition, IRBs struggle to interpret whether and how the criteria should be applied in order to grant a full waiver of informed consent.

SACHRP proposes modification of 45 CFR Part 46.116 in order to: (1) consolidate the elements of informed consent at §116 (a) and (b) into one comprehensive list of elements; (2) empower IRBs to waive selected elements of consent when deemed appropriate by the IRB; and (3) clarify the circumstances in which an IRB may grant a complete waiver of informed consent.

The proposed restructuring of 45 CFR Part 46.116 would not erode the ethical foundation embodied in informed consent. Modification of the regulations would instead permit IRBs to more consistently grant partial or complete waivers of informed consent without impinging on the ethical validity of the consent process or the research itself. These waivers are already permitted in the existing regulations, but nuances in the language have deterred IRBs from exercising the flexibility that the regulations were intended to provide.

Therefore, SACHRP recommends the following new language for inclusion in 45 CFR 46:

§46.116 General requirements for informed consent.
Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

> *(1) A statement that the study involves research, an explanation of the purposes of the research, a description of procedures that subjects*

will be asked to undergo with emphasis on those procedures that are directly relevant to a decision to participate, and identification of any procedures that are experimental;
(2) A description of any reasonably foreseeable risks or discomforts to the subject;
(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
(4) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights; and
(5) A statement that participation is voluntary, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Optional elements of informed consent. When appropriate, one or more of the following elements of information may also be provided to each subject. In the event an optional element is not to be included, it is not necessary to determine or document that the waiver criteria under paragraph (c) or (d) of this section are met:

(1) A disclosure of appropriate alternative procedures or courses of treatment, that might be advantageous to the subject;
(2) A statement describing the extent to which confidentiality of records identifying the subject will be maintained;
(3) A statement of whether medical treatment is available if injury occurs, where further information may be obtained, and whom to contact in the event of a research-related injury to the subject.
(4) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
(5) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
(6) Any additional costs to the subject that may result from participation in the research;
(7) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(8) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject; and
(9) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the basic elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designated to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not be reasonably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the basic elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research, or the component of the research related to the proposed waiver or alteration of consent, involves no more than minimal risk to the subjects and is reasonable in relation to the benefits of the research;

(2) When the request for a waiver involves access to materials (data, documents, records or specimens) the IRB should consider the following:

a. the minimum necessary information to accomplish the research, including the need for identifiers;

b. the sensitivity of the information; and

c. provisions in place to protect confidentiality;

(3) The waiver or alteration of consent has important ethical or scientific justification. For example: (i) scientific validity would be compromised if consent was required because it would introduce bias to the sample selection; or (ii) subjects' behaviors or responses would be biased, such that conclusions would not be meaningful; or (iii) the consent procedure would itself create additional threats to privacy that would otherwise not exist, or

there is risk of inflicting psychological, social or other harm by contacting individuals or families;

(4) The waiver or alteration of consent should not be justified solely on the basis of convenience, cost or speed; and

(5) Whenever appropriate, subjects will be provided with previously undisclosed information, when such information is pertinent to their involvement.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.